

REMARKS/ARGUMENTS

Claims 1-24 remain pending.

Support for each amended claim is found throughout the originally filed specification and the originally filed claims.

Upon entry of the amendment, Claims 1-24 will be active.

No new matter is believed to have been added.

At the outset, Applicants note that 24 claims were presented for examination in the previously filed amendment of August 15, 2007, but that the Office, as described for example at page 3 of the Official Action of November 5, 2007, appears to provide an actual on the merits rejection of only Claims 1-21. As evidenced by the lack of any rejection of record for Claims 22-24, the Office appears to have not examined Claims 22-24 on the merits. Applicants respectfully request an examination on the merits of all presently active 24 claims.

Further, although pages 3-4 of the Official Action of November 5, 2007, note that Claims 1-21 are rejected for obviousness, the text of the obviousness rejection describes only the Office's rationale for the obviousness rejection of the claimed composition embodiments.

The Official Action provides no rationale for combining Nelson and Fritsch to arrive at the method of Claim 11, no justification as to how the combination of Nelson and Fritsch describe or suggest each and every element of Claim 11 and the claims depending therefrom, and no reason why one of ordinary skill in the art, were Nelson and Fritsch combinable and descriptive or suggesting of every element of method Claim 11, would expect the resultant method Claim 11, and the claims depending therefrom, to be successful.

Using the above described paragraph as a jumping off point, Applicants respectfully traverse the obviousness rejection of Claims 1-21 as being unpatentable over Nelson in view of Fritsch.

Applicants respectfully note that Claim 11, and the claims depending therefrom, submitted in the Amendment of August 15, 2007, are method claims.

The Official Action does not give any reason why one of ordinary skill in the art would combine Nelson and Fritsch to arrive at method Claim 11, no showing of how Nelson and Fritsch describe or suggest every element of method Claim 11 and the claims depending therefrom, and no suggestion why the combination of Nelson and Fritsch, either alone or for example, combined with knowledge of one of ordinary skill in the art, would motivate one of ordinary skill in the art to expect success in practicing the method of Claim 11.

A reason to combine references, description or suggestion of all claim elements, and expectation of success are basic parts of an obviousness rejection (see MEPE 2143). None of these parts of an obviousness rejection have been provided by the Office for method Claim 11 and the claims depending therefrom.

Accordingly, although the Office has nominally rejected Claims 11 and the claims depending therefrom for obviousness, the Office has not met the burden of showing that method Claim 11 and the claims depending therefrom are obvious in view of Nelson combined with Fritsch. The obvious rejection of method Claim 11, and the claims depending therefrom, is missing ALL essential parts of an obvious rejection, is therefore improper, and therefore should not have been made, and should now be withdrawn.

Emphasizing these points, Applicants note that present method Claim 11 is drawn to a method for improving the level of L-ascorbic acid in the eye of a subject in need thereof by topically administering a composition comprising a salt of L-ascorbic acid with a pharmaceutically acceptable organic base, and a pharmaceutically acceptable inert vehicle, to the eye of the subject in need thereof, in an amount sufficient to improve the level of L-ascorbic acid in the eye, wherein the pH of the composition ranges from 5.0 to 5.6.

Nelson is drawn to a method for sterilizing contact lenses (See the Abstract of Nelson). Fritsch is drawn to an effervescent ibuprofen preparation (See the Abstract of Fritsch). Nelson and Fritsch do not therefore describe or suggest the method of present Claim 11, and the claims depending therefrom, of “improving the level of L-ascorbic acid in the eye of a subject in need thereof by topically administering a composition...” Nelson and Fritsch do not describe or suggest each and every element of present method Claim 11, nor would one of ordinary skill in the art expect success using the method of Claim 11 based on the disclosures of Nelson and Fritsch. Withdrawal of the obviousness rejection of Claim 11, and the claims depending therefrom, is requested.

Applicants respectfully traverse the obviousness rejection of present Claims 1 and 24, and Claim 11, and the claims depending therefrom, as being unpatentable over Nelson in view of Fritsch. Present Claims 1, 11 and 24 include the feature that “the pH of the composition ranges from 5.0 to 5.6.” This feature is not described or suggested by Nelson and Fritsch, and in fact, it “taught away from” by both Nelson and Fritsch.

The Office, in failing to acknowledge this important distinction, finds itself unenviably taking a position contrary to that of the Court of Appeals for the Federal Circuit and the MPEP.

MPEP 2141.03 VI describes, in part, that “a prior art reference must be considered in its entirety, i.e., as a whole, including positions that would lead away from the claimed invention.” (Note: emphasis on the word whole is the MPEP’s).

MPEP 2144.05 III describes, in part, that “a *prima facie* case of obviousness may also be rebutted by showing that the art, in any material aspect, teaches away from the claimed invention.”

In In re Gurley, 27 F.3d 551 31 USPQ2d 1130 (Fed. Cir. 1994), the Federal Circuit held that “A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.”

In the present case, both Nelson and Fritsch teach away, in a material aspect, from the feature of present Claims 1, 24 and 11, “that the pH of the composition ranges from 5.0 to 5.6.” Accordingly, Claims 1, 24 and 11, and the claims depending therefrom, are not obvious in view of Nelson and Fritsch.

Nelson, at column 3, lines 46-48, describes “In addition the pH of the solution is critical. If the solution pH is outside of the range of pH 6-9, the lenses will be adversely affected.”

The examples of Fritsch, describe a pH of 6.8 and 6.8 (see Examples 1 and 2, at column 4, of Fritsch), as well as a pH of “about 6.7” in Claim 2. Further, Fritsch describes that it is “conventionally known, in the art, that a pH of 6.8 to 7.2 is necessary to keep [the]...ibuprophen in solution” (See Fritsch, column 1, line 66-column 2, line 2).

Accordingly, one of ordinary skill in the art, to quote the Federal Circuit “would be led in a direction divergent from the path that was taken by the applicant,” by Fritsch and Nelson, because Fritsch and Nelson both show a criticality of keeping the pH at a range of 6-9, more preferably from about 6.7 to 7.2. Fritsch and Nelson, in describing the criticality of keeping the pH in the above described ranges “so that the ibuprophen stays in solution” and so that “the lenses are not adversely effected,” “teach away,” according to the Federal Circuits’ definition, from the pH limitation of present Claims 1, 24 and 11, and the claims depending therefrom. As described above, this “teaching away” is exactly the kind of secondary consideration envisioned by the MPEP to rebut a *prima facie* case of obviousness.

Finally, MPEP 2143.01 V describes, in part, that “the proposed modification cannot render the prior art unsatisfactory for its intended purpose.” The obviousness rejection, as proposed by the office, renders the cited references unsatisfactory for their intended purposes. Accordingly, the obviousness rejection is improper. Withdrawal of the obviousness rejection of Claims 1, 24 and, and the claims depending therefrom is requested.

Applicants submit the present application is now in condition for allowance. Early notification to this effect is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.  
Norman F. Oblon



---

Charles J. Andres, Jr., Ph.D.  
Attorney of Record  
Registration No. 57,537

Customer Number

**22850**

Tel: (703) 413-3000  
Fax: (703) 413 -2220  
(OSMMN 06/04)